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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,923	04/30/2001	Patrick Kennedy	1022-11	4246

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EXAMINER

LEITH, PATRICIA A

ART UNIT	PAPER NUMBER
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1654

DATE MAILED: 06/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/845,923

Applicant(s)

KENNEDY, PATRICK

Examiner

Patricia Leith

Art Unit

1654

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-8, 10-22, 24-28 and 30-32 is/are pending in the application.
- 4a) Of the above claim(s) 1-3 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4-8, 10-19, 21-22, 24-28 and 30-32 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Claims 1-8, 10-22, 24-28 and 30-32 are pending in the application.

Claims 1-3 and 20 were previously withdrawn from the merits as being directed toward a non-elected invention.

Claims 4-8, 10-19, 21-22, 24-28 and 30-32 were examined on the merits.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4-8, 10-19, 21-22, 24-28 and 30-32 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a carrier and a composition comprising the elements of the claims (i.e., glass, fruit shell) does not reasonably provide enablement for a composition or carrier which is able to abrade the

Art Unit: 1654

site and circulate at least one of a toxin and venom'. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make or use the invention commensurate in scope with these claims.

Applicant's arguments were fully considered, but not found persuasive for the following reasons.

Applicant argues that 'the composition consisting of an effective amount of abrasive ingredient and a carrier is able to contact and draw out any foreign body deposited at a site of an insect bite....'the allergenic material can be withdrawn rapidly from the body before getting into the bloodstream'" and therefore concludes that "the present specification fully enables the present pharmaceutical composition" (p. 10, Arguments). However, the statement 'the allergenic.....before getting into the bloodstream' appears to be speculative, especially considering that the ingredients in the claims as listed are not known for such functions.

Applicant argues that "The examiner further erroneously states that there is not one working example in the specification that demonstrates that any of the claimed composition which include abrasive ingredients such as a gum or a lubricant will actually perform commensurate in scope with the present claimed invention and further cites the record of the prior art" (p.11, Arguments). However, Applicant does not point out anywhere in the specification where there are any working examples.

Applicant argues that it is not the carriers which abrade the site and circulate a venom/toxin out of the site, but the application by a user which provides for such a function (p. 11, Arguments). This argument respectfully fails to remedy the outstanding rejection for the following reason: whether the composition is applied by a user is inconsequential in the matter at hand. The Examiner respectfully disagrees that the composition will actually perform as Instantly claimed – ‘is able to...circulate at least one of a toxin and venom out from said site’ is not enabled within the Instant specification. What toxins and venoms are circulated out of the wound/bite site with which combination of ingredients found in the Instant claims? Applicant argues that ‘...the Examiner further erroneously states that the state of the art is unpredictable” but does not provide any indication that any of the Instantly claimed compounds/compositions were known for circulating toxins/venoms from a wound site, and also do not provide any convincing data as such. Although Applicant cites the Instant specification (Second paragraph, p. 11, Arguments), again, this is considered unsubstantiated speculation as it is not verifiably shown in the Instant specification.

Applicant argues that “Applicant agrees that any cleaved toxins would not be able to physically leave the site without manual removal. However, this is not the thrust or the intention of the present claimed invention” (p. 12, Arguments). However, the claims clearly state ‘able to abrade the cite and circulate at least one of a toxin and a venom out from said site’, wherein ‘able’ is refering to the applied composition. Thus,

Art Unit: 1654

Applicant admits that the composition will not perform this function of circulating a toxin or a venom out from said site.

One of ordinary skill in the art would not know how to find or make such a special combination of elements to perform the intended use of the claimed invention; is the glass a special glass? How does it differ from the prior art of Lee et al? As clearly admitted by Applicant under the arguments for the 102 rejection (*infra*), the composition disclosed by Lee et al. is allegedly different from the Instant invention. If it is different in composition, the Examiner cannot see any difference. Thus, to perform the intended use of the claim, the skilled artisan would need to perform tedious trial and error protocols involving time and money in order to practice the claimed invention because there is no suggestion in the Instant specification or the prior art how the claimed invention would actually circulate a toxin or a venom away from a bite/sting.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 4, 6, 10, 11, 21, 22, 24, 25, 26, 30 and 31 remain rejected under 35 U.S.C. 102(b) as being anticipated by Lee (WO 99/37287) for the reasons of record.

It is noted that the claims were examined on the merits for their enabled scope, namely, a pharmaceutical/cosmetic agent.

Applicant argues that "...the bioactive glass of Lee is not analogous to the abrasive ingredient disclosed by the present claimed invention. While the abrasive ingredient of the present claimed invention includes glass, the function of the glass of the present claimed invention is to "abrade the site and circulate out at least one of a toxin and venom from said site" (pp. 14-15, Arguments). Again, it is reiterated that the claims were examined on their enabled scope which is a pharmaceutical/cosmetic agent which does not include the language 'able to abrade.....venom from said site'.

Applicant has not provided any evidence or persuasive arguments to substantiate the allegation that the composition of Lee is not analogous to the presently claimed invention. 'A composition is a composition' *In re Best*. Applicant has not verifiably demonstrated that the composition of the Instant claims is a different composition than that disclosed by Lee. What about the composition is different? It is noted that even if the composition claims were searched on the merits with regard to their non-enabled scope, it is the burden of the Applicant to show why the prior art compositions are different in physical structure/characteristics in order to overcome the

Art Unit: 1654

rejection at hand. In the Instant case, Applicant alleges that it is the composition's ability to 'abrade the site...circulate...venom from said site' which renders the Instantly claimed composition different from the prior art, however, this ability has not been substantiated within the Instant specification.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 8, 27 and 28 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (WO 99/ 37287) as applied to claims 4, 6, 10, 11, 21, 22, 25, 26, 30 and 31 above for the reasons of record.

Again, Applicant's principal argument is that Lee does not disclose where the composition is 'able to abrade....venom from said site'. Again, the claims were searched on the merits for their enabled scope which does not include this language.

Art Unit: 1654

Claims 5, 12-19 and 32 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Lee (WO 99/ 37287) as applied to claims 4, 6, 10, 11, 21, 22, 25, 26, 30 and 31 above, and further in view of Rubin (US 5,543,149) for the reasons of record.

Again, Applicant's principal argument is that Lee and Rubin do not disclose where the composition is 'able to abrade....venom from said site'. Again, the claims were searched on the merits for their enabled scope which does not include this language.

From the teachings of the references, it is apparent that one of ordinary skill in the art would have had a reasonable expectation of success in producing the claimed invention. Therefore, the invention as a whole was *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, as evidenced by the references, especially in the absence of evidence to the contrary.

No Claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Patricia Leith whose telephone number is (571) 272-0968. The examiner can normally be reached on 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Art Unit: 1654

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Patricia Leith
Primary Examiner
Art Unit 1654

05/23/05

A handwritten signature in black ink, appearing to read 'Patricia Leith', is written over the typed name and title.